UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANGELA ROSE SULLIVAN,

Plaintiff,

-against-

AVENTIS, INC.,

Defendant.

No. 14-cv-2939-NSR

OPINION & ORDER

NELSON S. ROMÁN, United States District Judge

Plaintiff Angela Rose Sullivan brings this action against Defendant Aventis, Inc. alleging claims for design defect, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, negligence, fraud, negligent misrepresentation, negligence *per se*, and unjust enrichment. Defendant moves to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the following reasons, Defendant's motion is GRANTED in part and DENIED in part.

FACTUAL ALLEGATIONS

This is a pharmaceutical products liability action based on Plaintiff's mother's use of a fertility drug called Clomid. Clomid was approved by the Food and Drug Administration ("FDA") on February 1, 1967, and is one of the oldest fertility treatments available. (Second Am. Compl. ¶ 9, ECF No. 38.) Clomid was designed, manufactured, and marketed by Defendant, Defendant's affiliates, Defendant's predecessors-in-interest, and/or Defendant's

affiliates' predecessors-in-interest.[1] (*Id.* ¶¶ 3-6, 9.) Clomid works by inhibiting the "negative feedback of estrogen on gonadotropin production" to "induce ovulation for the purpose of pregnancy." (*Id.* ¶ 8.) In October 1992, Plaintiff's mother was prescribed and took Clomid "with the intent that it help her conceive" and "conceived shortly thereafter." (*Id.* ¶¶ 10-11.) Plaintiff was born on July 16, 1993. (*Id.* ¶ 14.) Within a few months, she had been diagnosed with birth defects including a ventricular septal defect, a patent foramen ovale, hypothyroidism, and tachycardia. (*Id.* ¶¶ 15-21.) Plaintiff alleges that, due to an extended half-life, Clomid was still present in her mother's "maternal circulation" during Plaintiff's gestation. (*Id.* ¶ 13.) Plaintiff describes studies, papers, and actions by the FDA and Defendant from the 1960s through the present that purportedly show that Clomid may cause birth defects and that Defendant knew or should have known of these risks. (*Id.* ¶¶ 23-56.) Defendant allegedly failed to warn physicians and consumers of these risks, and instead represented "in its package inserts and other product labeling that 'no causative evidence of a deleterious effect of Clomid therapy on the human fetus has been seen.'" (*Id.* ¶ 58.) Plaintiff alleges that a design or manufacturing defect, misrepresentation, and/or failure to warn caused her injuries. (*Id.* ¶¶ 67-143.)

STANDARD ON A MOTION TO DISMISS

To survive a motion to dismiss, a complaint must supply "factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). In other words, the complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual

[1] For purposes of this motion, the Court will refer to all of these entities as "Defendant," because Defendant's motion to dismiss is not based on any defense related to Defendant's corporate history or position in a corporate hierarchy.

content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In applying this standard, a court should accept as true all well-pleaded factual allegations, but should not credit "mere conclusory statements" or "[t]hreadbare recitals of the elements of a cause of action." *Id.*

DISCUSSION

The thrust of Defendant's motion is that Plaintiff's claims, though artfully pleaded, are substantively indistinguishable from claims for wrongful life, which is not a recognized cause of action under New York law. Defendant also asserts that Plaintiff's design defect claim is preempted by federal law and barred by comment *k* to the Restatement (Second) of Torts § 402A. Finally, Defendant argues that the following claims are inadequately pleaded or legally barred: design defect, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, fraud, negligent misrepresentation, and unjust enrichment.

I. Wrongful Life

In *Becker v. Schwartz*, the New York Court of Appeals rejected wrongful life as a cause of action under New York law. 46 N.Y.2d 401, 410-12 (1978). In the lead case, the plaintiff was the mother of a child born with Down syndrome. *Id.* at 405. The mother asserted that her physicians negligently failed to inform her of the increased risk of Down syndrome in children born to women of her age, or of the availability of an amniocentesis test to determine whether the fetus would be born with the condition. *Id.* at 405-06. In *Park v. Chessin*, a companion case decided pursuant to the same opinion, the plaintiff mother gave birth to a child who, afflicted with polycystic kidney disease, died five hours later. *Id.* at 406-07. Her physicians thereafter erroneously told her that polycystic kidney disease was not hereditary and that her chances of having another child with the disease were "practically nil." *Id.* at 407. Relying on that advice,

the mother conceived another child who was born with the same condition and survived only two years and six months. *Id.*

The New York Court held that the parents in these cases could not recover on behalf of their children for two reasons.[2] Implicit in the claims in each case was that if the defendant physicians had not been negligent, the child would not have existed at all, because the parents would not have conceived or, if pregnant, would have terminated the pregnancy. *Id.* at 410-11. Any "injury" suffered by the children was not legally cognizable, then, because recognizing such an injury would require resolving the philosophical or theological "mystery" of whether "nonexistence" is preferable to impaired existence. *Id.* at 411. Relatedly, the claims presented the "hurdle" of calculating damages based on a comparison of impaired existence with nonexistence. *Id.* at 411-12. Some commentators term this line of reasoning the "nonexistence problem." *See, e.g.*, F. Allan Hanson, *Suits for Wrongful Life, Counterfactuals, and the Nonexistence Problem*, 5 S. Cal. Interdisc. L.J. 1, 3-4, 22 (1996).

Prenatal torts, in contrast to wrongful life claims, are recognized causes of action under New York law. Thus, where "a pregnant woman is injured through negligence and the child subsequently born suffers deformity or other injury as a result, recovery therefor may be allowed to the child, provided the causal relation between the negligence and the damage to the child be established by competent medical evidence." *Woods v. Lancet*, 303 N.Y. 349, 351 (1951); *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 213 (1991) ("[E]very State currently allows children born alive to recover in tort for prenatal injuries caused by third parties . . . ."). New York courts have distinguished

[2] The New York Court also held that the parents could not recover for their own emotional and psychological harm, but could recover for medical expenses they had incurred and would continue to incur for the child's care and treatment. *Becker*, 46 N.Y.2d at 411-13. These holdings are irrelevant to the instant motion because Plaintiff stands in the position of the child, and no claim is asserted on behalf of her parents.

prenatal torts from wrongful life on the basis of whether the relevant counterfactual is "nonexistence" or a healthy child. For example, in *Sheppard-Mobley ex rel. Mobley v. King*, the defendant physicians allegedly erroneously advised an expecting mother that her fetus would die or suffer "terrible" birth defects if carried to term because of the presence of fibroids in the mother's uterus. 4 N.Y.3d 627, 634-35 (2005). The physicians administered methotrexate to the mother in an attempt to terminate the pregnancy, but the treatment was unsuccessful and the child was born with severe birth defects allegedly caused by the methotrexate. *Id.* The New York Court recognized the infant plaintiff's claim as a prenatal tort, and distinguished it from *Becker* on the basis that, but for the defendants' negligence, "[the mother] would not have undergone methotrexate treatments and she would have given birth to a healthy child." *Id.* at 638; *see also Hughson v. St. Francis Hosp. of Port Jervis*, 459 N.Y.S.2d 814, 815 (App. Div. 1983) ("Unlike the infants in *Becker* and its companion case of *Park v. Chessin*, who would assertedly have chosen never to have been born at all rather than to have been born with Down's Syndrome or polycystic kidney disease, the infant at bar would presumably have been born normal and healthy but for the appellants' wrongful act.").

Some authorities distinguish wrongful life claims from prenatal torts on the basis of whether the defendant's negligence caused the birth defect, and Plaintiff urges the Court to apply that distinction here. *See Morgan v. Christman*, No. CIV. A. 882311O, 1990 WL 137405, at *3 (D. Kan. July 20, 1990). For example, the District of Kansas in *Morgan*, construing Kansas law, reasoned that in a traditional wrongful life claim, the physician's negligence does not "actually" cause the child's impairment.[3] *Id.* The claimants in *Morgan*, by contrast, alleged that their mother's use of Clomid caused their multiple gestation, premature births, and resulting

[3] Though some may argue that the impairment *is* caused by the defendant's negligence even in a wrongful life action because without the defendant's negligence, neither the child nor the impairment would have existed.

impairments, which, in that court's opinion, adequately distinguished their claims from a wrongful life action.[4] *Id.* As attractive as this distinction may be, it appears that it may be foreclosed under New York law by *Spano v. Bertocci*, 749 N.Y.S.2d 275, 278 (App. Div. 2002) and *Paretta v. Medical Offices for Human Reproduction*, 760 N.Y.S.2d 639 (Sup. Ct. 2003), two cases in which New York courts rejected claims, citing *Becker*, in which the defendants' negligence caused both the birth defect and the birth.[5] But the Court need not reach that question because, as explained in the following paragraphs, Plaintiff's claims do not necessarily raise the nonexistence problem, which adequately distinguishes them from wrongful life claims.

The thrust of Plaintiff's design defect theory is that Clomid could feasibly have been designed such that it would have helped Plaintiff's mother conceive with a substantially smaller risk of harm to Plaintiff. The relevant counterfactual, then, is that if Clomid had not been defectively designed, Plaintiff would have been born healthy notwithstanding her mother's use of Clomid. This calls for comparing Plaintiff to a healthy child—a task that courts routinely entertain—and the Court need not confront the injury problem or the obstacle of "calculation of

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[4] The claims in *Morgan* also avoided the nonexistence problem to some extent. The court explained in a footnote:

> While a wrongful life plaintiff argues that he or she would have no life but for the defendant's conduct, we aren't convinced from the record that Mrs. Morgan would not have given birth to any children absent the administration of clomid by defendant. Defendant has failed to establish that in lieu of the multiple pregnancy, Mrs. Morgan would not have given birth to at least one child. Thus, there may have been life regardless of defendant's alleged negligence, negligent misrepresentation, and failure to obtain consent.

1990 WL 137405, at *2 n.1. It is worth pointing out, though, that under the plaintiff's theory in *Morgan*, at least one of the children would not have existed at all but for the defendant's negligence.

[5] Although *Spano* and *Paretta* are not New York Court of Appeals decisions, they lend insight into how the New York Court of Appeals might rule if presented with the issue. *See Travelers Ins. Co. v. 633 Third Assocs.*, 14 F.3d 114, 119 (2d Cir. 1994) ("Where the substantive law of the forum state is uncertain or ambiguous, the job of the federal courts is carefully to predict how the highest court of the forum state would resolve the uncertainty or ambiguity."); *id.* ("[F]ederal authorities must apply what they find to be the state law after giving 'proper regard' to relevant rulings of other courts of the State."). Plaintiff's only citation to the contrary is the New York Court of Appeals' *dictum* that the basis for *Becker* was "in part because the doctor had not caused the defective condition of the child, but merely failed to detect it during the prenatal period." *Kennedy v. McKesson Co.*, 58 N.Y.2d 500, 519 (1983). But *Kennedy* did not expand the concept of prenatal tort to include cases in which the defendant's negligence caused the birth as well as the birth defect.

damages dependent upon a comparison between the Hobson's choice of life in an impaired state and nonexistence," *Becker*, 46 N.Y.2d at 411-12.[6]

Plaintiff's failure to warn theory is a closer question, but at this stage of the proceedings, the Court will not dismiss it. The relevant counterfactual is that, if Plaintiff's mother had been adequately informed of Clomid's risks, she would not have taken Clomid. But that does not necessarily mean that she would not have conceived naturally. Clomid allegedly functions by "induc[ing] ovulation for the purpose of pregnancy." (Second Am. Compl. ¶ 8.) Plaintiff does not allege that her mother was infertile or that she was able to conceive only through the use of Clomid. Instead, she alleges that her mother "took the fertility drug, Clomid [*sic*] with the intent that it help her conceive [and] conceived shortly thereafter." (*Id.* ¶¶ 10-11.) Construing the allegations in the light most favorable to the Plaintiff, there is a plausible counterfactual that Plaintiff would have been born without the use of Clomid (and therefore, without her complained-of impairments).[7]

II. Other Asserted Bases for Dismissal

A. Design Defect

1. Preemption

Plaintiff's design defect claim is not preempted. Because federal law is "the supreme Law of the Land," U.S. Const. art. VI, cl. 2, "Congress has the power to preempt state law,"

[6] The same is likely true of Plaintiff's manufacturing defect theory, but as explained *infra*, it has not been adequately pleaded. *See infra* Part II.B.

[7] To be clear, as Plaintiff asserts claims only on her own behalf, the Court expresses no opinion on whether a parent would have an individual claim for medical expenses or psychological or emotional harm given the same facts. The Court also expresses no opinion on whether it would reach the same conclusion had Plaintiff's parents used a different method of assisted reproductive technology (such as the *in vitro* donor procedure in *Paretta*). Furthermore, although Plaintiff alleges that her mother took Clomid prior to conception, Plaintiff alleges that the drug remained in her mother's system during gestation and harmed Plaintiff *in utero*. Therefore, the Court expresses no opinion on whether the same or similar harms would state a claim if they had occurred preconception. *See Enright by Enright v. Eli Lilly & Co.*, 77 N.Y.2d 377, 389 (1991) (declining to recognize a claim that the plaintiff's birth defects were caused by a drug that the plaintiff's grandmother ingested); *Albala v. City of New York*, 54 N.Y.2d 269, 271 (1981) (declining to recognize a claim that the child's birth defects were caused by the defendants' negligent perforation of the mother's uterus during an abortive procedure performed preconception).

Arizona v. United States, 132 S. Ct. 2492, 2500 (2012). In interpreting the presence and scope of preemption, a court starts with the "assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). But in every preemption case, "the purpose of Congress is the ultimate touchstone." *Id.* (internal quotation marks omitted).

"The Supreme Court has recognized three typical settings in which courts will find that Congress intended to preempt state law." *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 725 F.3d 65, 96-97 (2d Cir. 2013), *cert. denied sub nom. Exxon Mobil Corp. v. City of New York, N.Y.*, 134 S. Ct. 1877 (2014). "First, when Congress expressly provides that a federal statute overrides state law, courts will find state law preempted if, applying standard tools of statutory construction, the challenged state law falls within the scope of congressional intent to preempt." *Segedie v. Hain Celestial Grp., Inc.*, No. 14-CV-5029 NSR, 2015 WL 2168374, at *2 (S.D.N.Y. May 7, 2015) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). Second, when Congress legislates so comprehensively in one area as to "occupy the field," courts may infer from the federal legislation that Congress intended to preempt state law in that entire subject area. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). "Third, when neither of the first two categories applies but state law directly conflicts with the structure and purpose of a federal statute, [courts] may conclude that Congress intended to preempt the state law." *MTBE*, 725 F.3d at 96-97. Courts may find a conflict with preemptive effect only in two circumstances: first, when "compliance with both federal and state regulations is a physical impossibility," and second, when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 132 S. Ct. at 2501 (internal quotation marks omitted); *see also MTBE*, 725 F.3d at 97.

Defendant asserts that Plaintiff's design defect claim is preempted under *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (5-4), which concerned the applicability of impossibility preemption.[8] *Bartlett* held that the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and FDA regulations preempt "state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling." *Bartlett*, 133 S. Ct. at 2479. The Court first observed that New Hampshire's design defect law "requires manufacturers to ensure that the products they design, manufacture, and sell are not 'unreasonably dangerous.'" *Id.* at 2474. New Hampshire courts considering whether a drug is "unreasonably dangerous" employ a "risk-utility" approach, which balances numerous nonexclusive factors including: the drug's usefulness, the ability to reduce the drug's risk of danger without significantly affecting its efficacy or cost, and the presence and efficacy of a warning. *Id.* at 2475. The Court explained that two of these factors—the drug's usefulness and the ability to reduce its risk of danger—implicate the drug's chemical design and active ingredients. *Id.* But it would have been impossible, in the Court's opinion, for the drug manufacturer to design the particular generic drug in *Bartlett* any differently for two reasons: (1) the FDCA and FDA regulations require generic drugs to be "chemically equivalent," "bioequivalent," and equivalent in "rate and extent of absorption" to an FDA-approved brand-name drug, and (2) the drug in question was chemically incapable of being redesigned because of its simple composition. *Id.* The Court explained that because redesign was impossible, the only way for the manufacturer to "escape liability" would be to "ameliorate the drug's 'risk-utility' profile . . . [by strengthening] 'the presence and efficacy of [the drug's] warning' in such a way that the warning 'avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses.'" *Id.* (last alteration in

[8] Defendant does not move on the basis of express, field, or obstacle preemption.

original). Put differently, New Hampshire design defect claims concerning generic drugs impose on manufacturers a duty to alter the drug's label. *Id.* The Court concluded that these claims were preempted because it is impossible to comply with a duty to alter the label of a generic drug without violating federal laws requiring generic drug labels to be the same as the FDA-approved label for the corresponding brand-name drug. *Id.* at 2476-77. As the following paragraphs explain, the reasoning in *Bartlett* does not apply here.

The Court begins by identifying Defendant's duties under New York law. *See id.* at 2473. Under New York law, "[i]n order to establish a prima facie case in strict products liability for design defects, the plaintiff must show that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury." *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 107 (1983). New York, like New Hampshire, follows a "risk-utility" approach to determining whether a product is not reasonably safe, which calls for consideration of several factors:

> (1) the utility of the product to the public as a whole and to the individual user; (2) the nature of the product—that is, the likelihood that it will cause injury; (3) the availability of a safer design; (4) the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced; (5) the ability of the plaintiff to have avoided injury by careful use of the product; (6) the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff; and (7) the manufacturer's ability to spread any cost related to improving the safety of the design.

Id. at 109. "The purpose of risk/utility analysis is to determine whether the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design." *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997); *Bolm v. Triumph Corp.*, 422 N.Y.S.2d 969, 975 (App. Div. 1979) ("The reasonableness of choosing among various alternatives and adopting the safest one feasible is not only relevant in a design defect action, it is

at the very heart of the case."). Brand-name drug manufacturers can thus avoid liability under New York law by choosing a safer design for a drug.

There is yet another way for brand-name drug manufacturers to avoid liability—they can strengthen a drug's warning label. Although New York has not adopted the "consumer expectations" test in evaluating design defect claims, *see Tomasino v. Am. Tobacco Co.*, 807 N.Y.S.2d 603, 606 (App. Div. 2005) ("The plaintiff's design defect causes of action as against the manufacturer appellants, therefore, were not, as they suggest, 'subject to dismissal based solely on the conclusion that, as a matter of law, after 1969 when warnings were required to be included on cigarettes, cigarettes were in the condition contemplated by consumers at the time of purchase.'"), one of the factors of the "risk-utility" analysis under New York law is "the degree of awareness of the potential danger of the product which reasonably can be attributed to the plaintiff." *Voss*, 59 N.Y.2d at 109. This factor is directly impacted by the strength of the drug's warnings. *See, e.g.*, *Jackson v. Bomag GmbH*, 638 N.Y.S.2d 819, 822-23 (App. Div. 1996) (holding that recovery for design defect was precluded by the plaintiff's awareness of a brochure advertising an optional safety feature that would have prevented the harm for the plaintiff's specialized use of the machine); *cf. Donuk v. Sears, Roebuck & Co.*, 859 N.Y.S.2d 701, 702 (App. Div. 2008) (holding that recovery for design defect for a snow thrower was precluded by warning labels cautioning the plaintiff against reaching into the machine's chute while the engine was running, which demonstrated that the plaintiff's own negligence was the sole proximate cause of the harm). Moreover, for drugs that are unavoidably unsafe,[9] drug manufacturers have

[9] There is a body of *dicta* for the proposition that New York law views all prescription drugs as unavoidably unsafe, *see Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90-91 (2d Cir. 1980); *Martin v. Hacker*, 83 N.Y.2d 1, 8 (1993); *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95 (App. Div. 1979); *Militrano ex rel. Militrano v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 769 N.Y.S.2d 839, 846-47 (Sup. Ct. 2003), *aff'd sub nom. Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506 (App. Div. 2006), but the New York Court of Appeals has not squarely addressed the issue. *See DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 621 n.8 (S.D.N.Y. 2012).

an affirmative defense to liability if the drugs are "properly prepared, and accompanied by proper directions and warning." *Martin v. Hacker*, 83 N.Y.2d 1, 8 (1993) (interpreting Restatement (Second) of Torts § 402A cmt. *k*). Therefore, a New York design defect claim concerning a brand-name drug imposes on manufacturers a duty to render a drug safer either by redesigning the drug or by strengthening the drug's warning to ameliorate its risk-utility profile or, in the case of unavoidably unsafe drugs, to mount a comment *k* defense.

The next step is to determine whether this state-law duty makes compliance with any federal law impossible. "Impossibility pre-emption is a demanding defense," *Levine*, 555 U.S. at 573, and it is not established here. Federal law, as the *Bartlett* Court pointed out and as Defendant argues, restricts a manufacturer from altering the design of a drug *post*-FDA approval. *Bartlett*, 133 S. Ct. at 2471 ("Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" (citing 21 C.F.R. § 314.70(b)(2)(i))). But counsel has cited no federal law that restricts a brand-name drug manufacturer from designing a reasonably safe product *prior* to FDA approval.[10] A manufacturer choosing among alternative designs for a brand-name drug is not subject to the federal "equivalence" restrictions that apply to generic drugs. *Cf. id.* (noting that generic drugs must be "chemically equivalent," "bioequivalent," and equivalent in "rate and extent of absorption" to an existing, FDA-approved brand-name drug). Furthermore, even if redesign is not feasible, there is no federal law that prevents a manufacturer from complying with its state-law duty by strengthening a brand-name drug's warning label (pre- or post-approval). For example, although generic drugs must bear the same label as an

[10] Construing the allegations in the light most favorable to Plaintiff, Plaintiff's allegations at this stage are likely broad enough to encompass the theory that Defendant should have chosen an alternative design prior to FDA approval. This may not be the case at the summary judgment phase.

FDA-approved brand-name equivalent, no corresponding labeling requirement applies to brand-name drugs. And the Supreme Court in *Levine* made it abundantly clear that a state-law duty to strengthen a drug's warning label in no way conflicts with federal statutory and regulatory labeling requirements for brand-name drugs. *Levine*, 555 U.S. at 568-72 (pointing out that the "manufacturer[, not the FDA,] bears responsibility for the content of its label at all times [and] is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market," and citing an FDA regulation that "provides that if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,' it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval"). Therefore, redesign or relabeling a brand-name drug is not impossible here, as it was for the generic drug in *Bartlett*.

For all of the above reasons, the design defect claims asserted here are not barred by impossibility preemption under *Bartlett*. The Western District of Wisconsin has reached roughly the same conclusion for similar reasons. *See Estate of Cassel v. Alza Corp.*, No. 12-CV-771-WMC, 2014 WL 856023, at *5 (W.D. Wis. Mar. 5, 2014). The Court acknowledges that the Western District of New York has applied *Bartlett* preemption to claims involving a brand-name drug. *See Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 169 (W.D.N.Y. 2014). But in that case, the plaintiffs conceded that their design defect claims were preempted and withdrew them; apparently no party argued that the *Bartlett* Court's reasoning does not logically extend to brand-name drugs. *Id.* And to the extent that the Eastern District of Missouri has reached a

conclusion inconsistent with this Court's decision, that case was construing Missouri law and is nonbinding. *Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1014 (E.D. Mo. 2014).

2. Comment *K* Defense

New York's interpretation of comment *k* to the Restatement (Second) of Torts § 402A does not bar the design defect claim. The New York Court of Appeals in *Martin* described the "comment *k*" defense as follows: "Although a prescription drug is by its nature an inherently unsafe product and would in the usual case impute strict liability to its manufacturer, a defense is provided against such liability when the drug is 'properly prepared, and accompanied by proper directions and warning.'" 83 N.Y.2d at 8 (quoting *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95 (App. Div. 1979), *aff'd*, 52 N.Y.2d 768 (1980)). The "comment *k* defense is unavailable for products negligently manufactured, negligently distributed or unaccompanied by proper warnings." *Id.* Here, Plaintiff has adequately pleaded a failure to warn claim. *See* Part II.C, *infra*. Accordingly, the design defect claim is not barred by comment *k* at this stage.[11] *See, e.g.*, *Williamson v. Stryker Corp.*, No. 12 CIV. 7083 CM, 2013 WL 3833081, at *8 (S.D.N.Y. July 23, 2013); *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 621 (S.D.N.Y. 2012).

3. Adequacy of the Pleadings

Plaintiff has adequately alleged a design defect claim. To state a claim for design defect a plaintiff must show that: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury." *Goldin v. Smith & Nephew, Inc.*, No. 12 CIV. 9217 JPO, 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24, 2013). Plaintiff alleges that her mother took Clomid and that due to an extended half-life, the medicine remained in her mother's system

[11] The Court therefore need not predict whether New York courts would adopt the minority view (assumed by Defendant's argument) that all prescription drugs are unavoidably unsafe under comment *k*. *See supra* note 9.

during the period of Plaintiff's organogenesis, causing Plaintiff's birth defects. The Second Amended Complaint further identifies scientific authorities purportedly opining that Clomid can remain in the mother's system during gestation and can cause birth defects when exposed to a fetus. Plaintiff alleges that "safer alternative designs" existed that were "economically and technologically feasible" that would have "prevented and/or significantly reduced the risk of the Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product." It is plausible to infer that Plaintiff is referring to designs in which the drug does not remain in the mother's system during organogenesis. The above allegations are sufficient to place Defendant on notice of the nature of the Plaintiff's claims. Defendant argues that the *Iqbal-Twombly* standard demands more detail concerning how the design should have been altered and why it was feasible. Imposing such a standard would "require the plaintiff to possess technical or scientific knowledge about the inner workings of the product, which would contravene the notice pleading requirement of Federal Rule of Civil Procedure 8, even under the *Iqbal-Twombly* standard." *Williamson*, 2013 WL 3833081, at *4. The cases cited by Defendant are largely distinguishable because Plaintiff here has pleaded greater detail than the plaintiffs in those cases. *Cf., e.g.*, *DiBartolo*, 914 F. Supp. 2d at 622-23; *Lewis v. Abbott Labs.*, No. 08 CIV. 7480SCRGAY, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 578 (E.D.N.Y. 2012). Plausibility requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" of the alleged misconduct. *Twombly*, 550 U.S. at 556. That standard is met here.

B. Manufacturing Defect

Plaintiff's manufacturing defect claim fares differently. Plaintiff's entire theory of the case is that Clomid causes birth defects, not the particular dose of Clomid that Plaintiff's mother took. All factual allegations point to the inference that Clomid was defective, if at all, by design.

(*E.g.*, Second Am. Compl. ¶ 24 ("Defendant knew or should have known about these adverse side effects as early as 1962 [i.e., thirty years before Plaintiff's mother took the drug]."); *id.* ¶ 40 ("Merrell submitted a proposed draft of an amended package insert . . . [including] a warning that Clomid and/or its metabolites may remain in the body during early pregnancy in *every woman* who conceives during a treatment cycle." (emphasis added)); *id.* ¶ 46 ("Clomid impairs the biosynthesis of cholesterol by inhibiting the function of enzymes . . . .").) The lone suggestion of a manufacturing defect—paragraph 78 of the Second Amended Complaint—is formulaic and conclusory. And even in that paragraph, Plaintiff simply alleges that "*Clomid* contained manufacturing defects," i.e., Clomid generally. Nowhere does Plaintiff allege that the dose(s) administered to Plaintiff's mother deviated from other doses in any way. Although a plaintiff is permitted to plead in the alternative, Fed. R. Civ. P. 8(d)(2)-(3), those alternative claims must find support in factual allegations. Here, the pleadings allege no facts to raise a reasonable expectation that discovery will reveal a manufacturing defect in the doses of Clomid administered to Plaintiff's mother. Accordingly, Plaintiff's manufacturing defect claim must be dismissed.

C. Failure to Warn

Defendant's arguments as to the adequacy of Plaintiff's failure to warn allegations are unavailing. Defendant's citation to the learned intermediary doctrine as a basis for dismissal must fail because Plaintiff does, in fact, allege that Defendant failed to warn Plaintiff's prescribing physician of the purported dangers of Clomid. Defendant's proximate cause argument is unconvincing. *See Raney v. Owens-Ill., Inc.*, 897 F.2d 94, 95-96 (2d Cir. 1990) (proximate cause may be inferred from alleged circumstances). Accordingly, Plaintiff's failure to warn claim survives to the extent it is premised on Defendant's failure to warn Plaintiff's mother's physician.

D. Breach of Implied Warranty

Defendant's argument as to Plaintiff's claim for breach of implied warranty is largely premised on dismissal of her claims for design defect and manufacturing defect. As the Court has found that Plaintiff's design defect claim survives, these arguments are moot. Accordingly, the Court will not dismiss the claim for breach of implied warranty.

E. Breach of Express Warranty

Defendant's claim that Plaintiff failed to "state how the express warranty was made" is simply untrue. (*See* Second Am. Compl. ¶ 58.) Defendant also argues that Plaintiff failed to allege that she complied with New York's litigation-notice requirement, N.Y. U.C.C. § 2-607(3)(a), which requires express warranty claimants to notify the defendant of the alleged breach within a reasonable time after having discovered it. "[R]equiring notice is designed to defeat commercial bad faith, not to deprive a good faith consumer of his remedy." *Id.* § 2-607 cmt. 4. "[T]he sufficiency and timeliness of the notice is generally a question for the jury." *Tomasino v. Estee Lauder Cos. Inc.*, 44 F. Supp. 3d 251, 260 (E.D.N.Y. 2014). Moreover, "what constitutes a reasonable time for taking an action depends on the nature, purpose and circumstances of such action." *Id.* (internal quotation marks omitted). "New York cases applying N.Y. U.C.C. § 2-607(3) suggest that a plaintiff's pleadings may constitute reasonable notice in certain cases." *Id.* at 261 n.6. Plaintiff alleges that Defendant actively concealed the breach and that she did not know and could not have known of the alleged breach. (*See* Second Am. Compl. ¶¶ 63-66.) These allegations are sufficient, for now, to preserve the claim.

F. Fraud

Plaintiff's fraud claim must be dismissed because it is not pleaded with "particularity." Fed. R. Civ. P. 9(b). A fraud claimant must: "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the

statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Harsco Corp. v. Segui*, 91 F.3d 337, 347 (2d Cir. 1996). A plaintiff must allege "the who, what, when, where, and how" of the alleged fraud. *See also PNCEF, LLC v. Oz Gen. Contr. Co.*, No. CV-11-724(SJF)(ARL), 2012 WL 4344538, at *8 (E.D.N.Y. Aug. 2, 2012).

Plaintiff's opposition identifies two fraudulent statements: (1) that Defendant "widely advertised and promoted Clomid as safe and effective medication for us [*sic*] to induce ovulation for the purpose of pregnancy" and (2) that Defendant "represented in its package inserts and other product labeling that 'no causative evidence of a deleterious effect of Clomid therapy on the human fetus has been seen.'" Plaintiff's allegations with respect to the "advertise[ments] and promot[ions]" are wholly insufficient. Plaintiff does not allege which advertisements her mother saw, when she saw them, when they ran, the advertising medium (e.g., television, print, billboard), or what words were used. Plaintiff's allegations with respect to the representations on package inserts and "other product labeling" do allege the specific words used. But the Second Amended Complaint does not specifically allege that Plaintiff's mother read these representations (let alone *when* she viewed the "package inserts and other product labeling"), nor does the Second Amended Complaint specifically allege that Plaintiff's mother relied on the package insert or label (if she in fact read them) in deciding to take Clomid. *DDR Const. Servs., Inc. v. Siemens Indus., Inc.*, 770 F. Supp. 2d 627, 657-58 (S.D.N.Y. 2011) (a plaintiff must allege, *inter alia*, that "plaintiff believed and justifiably relied upon the statement and was induced by it to engage in a certain course of conduct"). Plaintiff identifies no authority that states that a court may infer reliance in these circumstances. Accordingly, this claim must be dismissed.

G. Negligent Misrepresentation

Defendant's sole proffered basis for dismissing the negligent misrepresentation claim is that Plaintiff was not in privity, or any relationship approaching privity, with Defendant, and that she has not alleged that she was a "known party" to Defendant or that Defendant undertook conduct linking it to her. *See DiBartolo*, 914 F. Supp. 2d at 624 (explaining that absent privity, a negligent misrepresentation claimant must allege "(1) an awareness by the maker of the statement that it is to be used for a particular purpose; (2) reliance by a known party on the statement in furtherance of that purpose; and (3) some conduct by the maker of the statement linking it to the relying party and evincing its understanding of that reliance"). This argument is logically incomplete on its face. Defendant does not explain why Plaintiff, rather than Plaintiff's mother, is the relevant person under these standards. Accordingly, the Court will not dismiss the claim on this basis.

H. Unjust Enrichment

The New York Court of Appeals recently clarified New York law on the availability of an unjust enrichment cause of action:

> [U]njust enrichment is not a catchall cause of action to be used when others fail. It is available only in unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff. Typical cases are those in which the defendant, though guilty of no wrongdoing, has received money to which he or she is not entitled. An unjust enrichment claim is not available where it simply duplicates, or replaces, a conventional contract or tort claim.

Corsello v. Verizon N.Y., Inc., 18 N.Y.3d 777, 790 (2012). The New York Court affirmed the trial court's dismissal of an unjust enrichment claim reasoning that because the plaintiffs had alleged actionable wrongs, "To the extent that these claims succeed, the unjust enrichment claim is duplicative; if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy

the defects." *Id.* at 791. Plaintiff has alleged actionable wrongs, and the unjust enrichment claim is based on identical facts. The unjust enrichment claim is dismissed.

CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss is GRANTED in part and DENIED in part, and Plaintiff's claims of manufacturing defect, fraud, and unjust enrichment are DISMISSED. Defendant shall have twenty-one days from the date of this Order to file responsive pleadings. An initial case management and scheduling conference pursuant to Fed. R. Civ. P. 16 is scheduled for September 30, 2015 at 11:00 a.m., at the United States Courthouse, 300 Quarropas Street, Courtroom 218, White Plains, New York 10601. The parties shall confer in accordance with Fed. R. Civ. P. 26(f) at least 21 days prior to the conference and attempt in good faith to agree upon a proposed discovery plan that will ensure trial readiness within six months of the conference date. The parties shall also complete a Civil Case Discovery Plan and Scheduling Order and bring it to the conference. The Court respectfully directs the Clerk to terminate the motion at ECF No. 41 and to amend the caption of this case in accordance with the first page of this Opinion.

Dated: August 12th, 2015
White Plains, New York

SO ORDERED:

NELSON S. ROMÁN
United States District Judge